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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	**PAPER NUMBER**
1647	11

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary

Application No.	Applicant(s)
09/800,198	Vernet et al.
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 26, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-49* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 38, 41, drawn to an isolated polypeptide and a pharmaceutical composition comprising said polypeptide, classified in class 530, subclass 350.

II. Claims 5-14, 39, 42, drawn to an isolated polynucleotide, an expression system, a host cell, a method of making the encoded protein and a pharmaceutical composition comprising said nucleic acid, classified in class 435, subclass 69.1.

III. Claims 15-18, 40, 43, drawn to an isolated antibody and a pharmaceutical composition comprising said antibody, classified in class 530, subclass 387.9.

IV. Claims 19-21, drawn to a method of determining the presence of nucleic acid in a sample, classified in class 436, sub class 504.

V. Claims 22-23, drawn to a method of identifying an agent that binds to a polypeptide by contacting said polypeptide with said agent, classified in class 435, subclass 7.

VI. Claim 24, drawn to a method of identifying an agent that modulates the expression of a polypeptide, classified in class 435, subclass 6.

VII. Claim 24, drawn to a method of identifying an agent that modulates the activity of a polypeptide, classified in class 436, subclass 501.

VIII. Claim 25, drawn to a method for modulating the activity of a polypeptide, classified in class 435, subclass 7.2.

IX. Claims 26-29, 48, drawn to a method of treating a pathological state in a mammal, by administering a polypeptide, classified in class 514, sub class 12.

X. Claims 30-33, 49, drawn to a method of treating a pathological state in a mammal by administering a nucleic acid, classified in class 514, sub class 44.

XI. Claims 34-37 drawn to a method of treating a FCTRX-associated disorder by administering an antibody, classified in class 424, sub class 134.1.

XII. Claim 44-47, drawn to a method for determining the presence of or predisposition to disease associated with altered levels of a polypeptide by measuring the level of expression of polypeptide, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of Group II can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of Group I can be used other than to make the antibody of Group III, such as used as a probe, or used therapeutically or diagnostically (e.g. in screening). Although the antibody of Group III can be used to obtain the nucleic acid of Group II, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically. A search from any of the above Groups would not necessarily reveal art pertinent to any other Group.

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the encoded polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions I and V, VII, VIII, are related as product and processes of use.. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptide of Group I as claimed can also be used to raise antibodies or can be used therapeutically.

Inventions I and IX, are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptide of Group I as claimed can also be used to raise antibodies or can be used diagnostically.

Inventions II and IV, VI, X, XII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polynucleotide of Group II as claimed can also be used to produce the encoded protein.

Inventions III and XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibody of Group III as claimed can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography).

Inventions II, III, are unrelated to inventions V, VII, VIII, IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case neither the polynucleotide of Group I, nor the antibody of Group III is used or produced in any of the methods of Groups V, VII, VIII, IX.

Inventions I, III, are unrelated to inventions IV, VI, X, XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case neither the polypeptide of Group I, nor the antibody of Group III, is used or produced in any of the methods of Groups IV, VI, XII, X.

Inventions I, II, are unrelated to inventions XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case neither the polypeptide of Group I, nor the polynucloetide of Group II, is used or produced in the method of Group XI.

Inventions IV-XII are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Additional Restriction Requirement

3. The claims of Groups I-XII recite a multitude of polypeptides (SEQ ID Nos: 2, 4, 6, 8, 13, 15, 17, 19, 21, 25) and polynucleotides (SEQ ID Nos: 1, 3, 5, 7, 9, 10, 11, 12, 14, 16, 18, 20, 22, 24). This constitutes a recitation of an implied, mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the polypeptides and polynucleotides are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.

Upon election of one of Groups I-XII Applicant is additionally required to elect a single polypeptide or polynucleotide sequence. This requirement is not to be considered as a requirement of an election of species, since each of the compounds recited in alternative from is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

4 Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wedensday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647

08 April 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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